

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Request for Nominations for Members on Public Advisory Committees in the Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the public advisory committees in the Center for Drug Evaluation and Research.

Nominations will be accepted for current vacancies and vacancies that will or may occur on the committees during the next 16 months.

FDA has a special interest in ensuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, and physically handicapped candidates. Final selection from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for receipt of nominations.

ADDRESSES: All nominations and curricula vitae should be sent to the addresses below.

FOR FURTHER INFORMATION CONTACT:

Regarding nominations, except for consumer representatives: John Treacy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: treacy@cder.fda.gov.

Regarding nominations for consumer representatives: Maureen Hess, Office of Consumer

Affairs (HFE-50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5006, e-mail: mhess@oc.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of members for the following 16 advisory committees for vacancies listed below. Individuals should have expertise in the activity of the committee.

1. *Advisory Committee for Pharmaceutical Science*: Two vacancies occurring immediately, two vacancies occurring October 31, 2001, and six vacancies occurring October 31, 2002, including that of the consumer-nominated member.
2. *Advisory Committee for Reproductive Health Drugs*: Four vacancies occurring immediately, four vacancies occurring June 30, 2001, and three vacancies occurring June 30, 2002.
3. *Anesthetic and Life Support Drugs Advisory Committee*: Five vacancies occurring immediately, and four vacancies occurring March 31, 2002, including that of the consumer-nominated member.
4. *Anti-Infective Drugs Advisory Committee*: Five vacancies occurring November 30, 2001, and three vacancies occurring November 30, 2002.
5. *Antiviral Drugs Advisory Committee*: Three vacancies occurring immediately, three vacancies occurring October 31, 2001, and two vacancies occurring October 31, 2002.
6. *Arthritis Advisory Committee*: Two vacancies occurring September 30, 2001, and four vacancies occurring September 30, 2002.
7. *Cardiovascular and Renal Drugs Advisory Committee*: Three vacancies occurring June 30, 2001, including that of the consumer-nominated member, and four vacancies occurring June 30, 2003.
8. *Dermatologic Drugs Advisory Committee*: Seven vacancies occurring immediately, four vacancies occurring August 31, 2001, and four vacancies occurring August 31, 2002, including that of the consumer-nominated member.

9. *Endocrinologic and Metabolic Drugs Advisory Committee*: One vacancy occurring immediately, one vacancy occurring June 30, 2001, and four vacancies occurring June 30, 2002.

10. *Gastrointestinal Drugs Advisory Committee*: Three vacancies occurring June 30, 2001, and two vacancies occurring June 30, 2002.

11. *Medical Imaging Drugs Advisory Committee*: Ten vacancies occurring immediately, three vacancies occurring June 30, 2001, and two vacancies occurring June 30, 2002, including that of the consumer-nominated member.

12. *Nonprescription Drugs Advisory Committee*: Four vacancies occurring immediately, including that of the consumer-nominated member, one vacancy occurring on May 30, 2001, and four vacancies occurring May 31, 2002.

13. *Oncologic Drugs Advisory Committee*: Two vacancies occurring June 30, 2001, and three vacancies occurring June 30, 2002.

14. *Peripheral and Central Nervous Systems Drugs Advisory Committee*: Seven vacancies occurring immediately.

15. *Psychopharmacologic Drugs Advisory Committee*: Two vacancies occurring June 30, 2001, and four vacancies occurring June 30, 2002, including that of the consumer-nominated member.

16. *Pulmonary-Allergy Drugs Advisory Committee*: Two vacancies occurring immediately, two vacancies occurring May 31, 2001, including that of the consumer-nominated member, and five vacancies occurring May 31, 2002.

Function

The functions of the 16 committees listed above are to review and evaluate available scientific, technical, and medical data concerning the safety and effectiveness of marketed and investigational human drugs for use in the area of medical specialties, indicated by the title of the committee, and to make appropriate recommendations to the Commissioner of Food and Drugs.

Criteria for Members

Persons nominated for membership on the committees described above must have adequately diversified research and/or clinical experience appropriate to the work of the committee in such fields as anesthesiology, surgery, internal medicine, infectious disease, asthma, rheumatology, microbiology, pediatrics, ophthalmology, cardiology, clinical/medical oncology, hematology, radiology, nuclear medicine, biostatistics, epidemiology, dermatopathology/immunodermatology, dermatology, psychopharmacology, neurochemistry, neuropharmacology, endocrinology, obstetrics and gynecology, reproductive endocrinology, gastroenterology, pharmacology, clinical pharmacology, hepatology, virology, pharmaceutical manufacturing, bioavailability and bioequivalence research, pharmacokinetics, neurology, psychiatry, psychology, neuropharmacology, neuropathology, pulmonary disease, allergy, immunology, clinical immunology, or other appropriate areas of expertise.

The specialized training and experience necessary to qualify the nominee as an expert suitable for appointment is subject to review, but may include experience in medical practice, teaching, research, and/or public service relevant to the field of activity of the committee. The term of office is up to 4 years.

Criteria for Consumer-Nominated Members

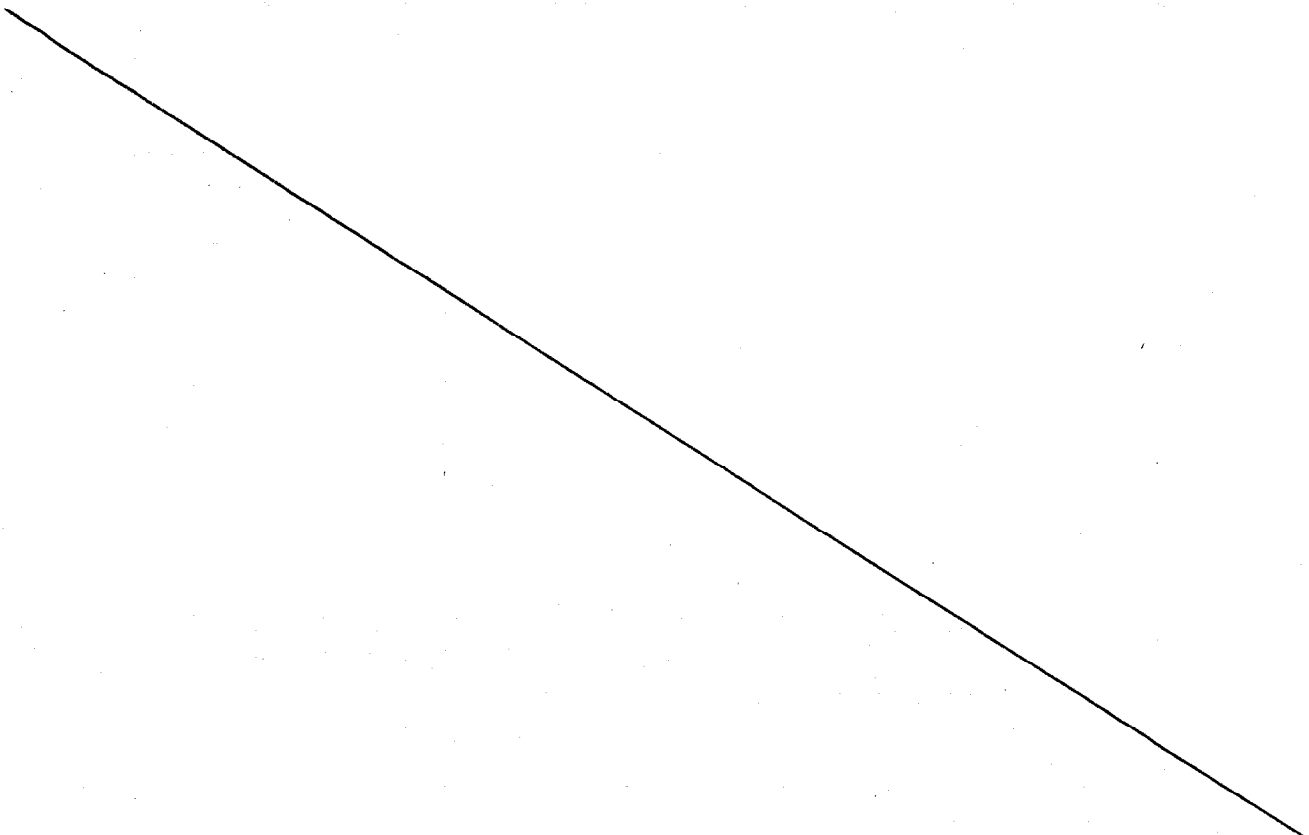
FDA currently attempts to place on each of the committees described above one voting member who is nominated by consumer organizations. These members are recommended by a consortium of 12 consumer organizations which has the responsibility for screening, interviewing, and recommending consumer-nominated candidates with appropriate scientific credentials. Candidates are sought who are aware of the consumer impact of committee issues, but who also possess enough technical background to understand and contribute to the committee's work. This would involve, for example, an understanding of research design, benefit/risk and the legal requirements for safety and efficacy of the products under review, and considerations regarding individual products. The agency notes, however, that for some advisory committees, it may require

such nominees to meet the same technical qualifications and specialized training required of other expert members of the committee. The term of office for these members is up to 4 years.

Nominations for all committees listed above are invited for consideration for membership as openings become available.

Nomination Procedure

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory committees. Nominations shall specify the committee for which the nominee is recommended. Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of conflict of interest.



This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 2, 01
May 2, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Moni Oliver

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